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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/017,479	12/12/2001	Robert A. Reenan	13407-012001 / 00-066	5194
26161	7590	04/20/2004	EXAMINER	
FISH & RICHARDSON PC 225 FRANKLIN ST BOSTON, MA 02110			KAPUST, RACHEL B	
			ART UNIT	PAPER NUMBER

1647

DATE MAILED: 04/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/017,479

Applicant(s)

REENAN ET AL.

Examiner

Rachel B. Kapust

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1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 31,32,53,54,56,58,59,61-71,73,75-80 and 82-103 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 31,32 and 82 is/are allowed.
- 6) ☒ Claim(s) 53,54,56,58,59,61-71,73,75-80 and 83-103 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>0204</u> . | 6) <input type="checkbox"/> Other: _____ |

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RESPONSE TO AMENDMENT

Applicant's amendment filed February 9, 2004 is acknowledged. Claims 1-30, 33-52, 55, 57, 60, 72, 74, and 81 have been canceled. Claims 31, 32, 53, 54, 56, 58, 59, 61-63, 66-68, 73, 75-77, 79, 80, and 82-84 are amended. Claims 85-103 are new. Claims 31, 32, 53, 54, 56, 58, 59, 61-71, 73, 75-80 and 82-103 are pending and under consideration. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

Claim Rejections/Objections Withdrawn

The objection to the specification as lacking sequence identifiers is withdrawn in response to Applicant's amendment to the specification and indication that corrections to the brief description of drawings were provided in the response filed July 7, 2003.

The specification is newly objected to because the use of the trademarks PBLUESCRIPT™ (p. 7) and SEPHAROSE™ (p. 31) have been noted in this application. They should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

The rejection of claim 81 under 35 U.S.C. 103(a) as being unpatentable over Sekine *et al.* (1998) *Am. J. Physiol.* 275: F298-F305 (submitted by Applicants in IDS), Pajor (1996), *Am. J. Physiol.* 270: F642-F648, and Chen *et al.* (1999), *J. Clin. Invest.* 103: 1159-1168 and further in view of Amara *et al.*, U.S. Patent No. 6,100,085 is withdrawn in response to Applicant's cancellation of this claim.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of claims 53, 59, 64-71, 83, and 84 under 35 U.S.C. 112, second paragraph is maintained for reasons of record on p. 3 of the office action of paper no. 0903. Applicants argue that evaluating an interaction between a test molecule and a transporter polypeptide encompasses evaluating “any interaction between the test molecule and the transporter polypeptide” (p. 12 of the response).

Applicant’s arguments have been fully considered but have not been found to be persuasive. All of the different types of interactions appear to require direct contact, *i.e.* binding of a test molecule with a transporter polypeptide. One of skill in the art would not know what other kinds of interactions Applicants intended to measure. The specification is silent as to types of interactions other than binding interactions. Thus, Applicants have not particularly pointed out nor distinctly claimed any methods of evaluating any interaction other than by evaluating a binding interaction. In addition, claim 53 is drawn to a method of evaluating an interaction of a test molecule with a transporter polypeptide by evaluating the interaction of the test molecule with the transporter polypeptide. Because the skilled artisan would not know what an “interaction” other than binding is, the skilled artisan would not know what to measure.

Claims 53, 54, 56, 58, 59, 61-71, 73, 75-80, and 83-103 are newly rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims as written are drawn to methods of “evaluating” interactions, cells, and libraries of compounds. “Evaluate” is a mental process that involves determining the value, significance, worth or condition of something (see *Webster's Revised Unabridged Dictionary*, © 1996, 1998 MICRA, Inc.). The claims do not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. One of skill in the art would not know the metes and bounds of “evaluate” because one of skill in the art would not know what steps are involved in “evaluating” an interaction or a cell or a library of compounds.

Claims 68-71 are newly rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 68 is drawn to a method of evaluating a library of compounds. The method further comprises contacting a transporter polypeptide with “a test molecule”. As written, it appears that the “test molecule” is a new molecule that is different from the compounds in the “library of compounds”. Claims 69-71 are rejected as being dependent on claim 68. The rejection could be obviated by amending the claim so that the method comprises contacting a transporter polypeptide with “a chemical compound from the library of chemical compounds”.

Claims 69 and 70 are newly rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 69 and 70 are dependent on claim 68, which is drawn to a method of evaluating a library of compounds. Claims 69 and 70 encompass the method of 68 wherein the method further comprises the step of selecting one or more members that either stimulate or inhibit the transporter polypeptide. However, the relationship of the steps of claims 69 and 70 to the method of claim 68 is unclear. One of skill in the art would not know when in the method of claim 68 to perform the additional steps provided by claims 69 and 70.

Claim 71 is newly rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 71 is dependent on claim 68, which is drawn to a method of evaluating a library of compounds. Claim 71 encompasses the method of claim 68 wherein the method further comprises contacting one or more members of the library to a cell and evaluating an aging symptom of the cell. The relationship of the step of claim 71 to the method of claim 68 is unclear. One of skill in the art would not know when in the method of claim 68 to perform the additional step provided by claim 71.

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Claims 67, 71, and 83-103 are newly rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims as written are drawn to methods of evaluating “aging symptoms”. The term is not defined by the claims and the specification does not provide a definition of aging symptoms. One skilled in the art would not know what processes Applicants intended to measure. From the specification, it appears the increased life span is a measurable indication of an aging symptom (see p. 43, Example 3). The claims potentially encompass far more than increased life span, but it is not clear from the specification what other indices may be included.

Claims 73 and 75-80 are newly rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are drawn to cells that “can express” a transporter polypeptide. By saying that the cells “can” express a transporter polypeptide, applicants imply that there would be conditions under which the transporter polypeptide is not being expressed. If the claims were meant to encompass conditions under which the transporter polypeptide were not expressed, one of skill in the art would not know how to use the methods under such conditions. The methods appear to only work when the transporter polypeptide is being expressed. The rejection could be obviated by amending the claims so that they are drawn to “a cell that expresses a transporter polypeptide”.

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Conclusion

Claims 31,32 and 82 are allowed.

Claims 53, 54, 56, 58, 59, 61-68, 70, 71, 73, 75-80, and 83-103 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rachel B. Kapust whose telephone number is (571) 272-0886. The examiner can normally be reached on Mon-Fri 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (571) 272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RBK
4/15/04


JANET A. [unclear]
PATENT EXAMINER